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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------|------------------|
| 10/525,626 | 02/24/2005 | Shigeaki Nishii | 18900-002US1 20051H/US | 9641 |
| 26211 | 7590 | 07/03/2006 | EXAMINER | |
| FISH & RICHARDSON P.C. P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022 | | | HAQ, SHAFIQUL | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1641 | |

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 10/525,626 | Applicant(s) NISHII ET AL. | |
| | Examiner Shafiqul Haq | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2006.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-31 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 12-31 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5/4/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendments filed March 29, 2006 is acknowledged and entered.
2. Claims 1-11 have been cancelled and new claims 12-31 have been added.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al (US 5,538,852).

Carlson et al. disclose competitive immunoassay methods for determining the amount of polychlorinated biphenyls (dioxins) in which chlorinated phenoxy (Formula I of front page, column 4; compound 15 of Fig.4 and claim 14) conjugates with BSA or KHL (see example 5) are used as competitor in the immunoassay method (column 11, lines 40-45). The chlorinated phenoxy conjugate with BSA and KSA

(Formula I of front page, column 4; compound 15 of Fig.4 and claim 14 and example 5) reads on the compound of formula (1) of instant claims 1-3. Note that Formula 1 (e.g. compound 15 of Fig.4) of reference compound when conjugated with KLH or BSA through carbodiimide mediated carboxyl activation (column 15, lines 55-57) reads on the compound of formula (1) of instant compound conjugated with peptide. The "polychlorinated biphenyl" analyte of claim 14 of Carlson et al. is encompassed by the "dioxins" analytes of claim 12 of this application. Carson et al. disclose that different immunoassay such as enzyme immunoassay, radioactive immunoassay etc. can be used with the competitor (column 11, lines 40-46 and column 6, lines 40-48). Carson et al. further disclose that the sensitivity of the immunoassay is expected to enhance by selecting a competitor that does not substantially duplicate the hapten (column 9, lines 35-47). Polychlorinated phenoxy conjugates have a lower affinity for anti-PCBs antibodies than the antibodies have to the polychlorinated biphenyls and therefore, polychlorinated phenoxy conjugates as competitor are preferred over biphenyl conjugate which results in improved detection sensitivity (column 9, lines 36-47; column 3, lines 15-54).

Carlson et al. do not disclose using competitor as a control in the immunoassay method but the use of control (standard) to obtain a calibration curve is a well known requirement for the performance of an immunoassay and therefore the use of such calibration curve by Carlson is implied. Since the competitor and analyte antigens bind similarly to the antibody, it would be presumed that either the analyte antigen or the competitor antigen could function equivalently as a control standard. However,

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improved assay sensitivity is to be expected from the use of the competitor of Formula 1 of Carlson et al. (See Carlson et al., col. 4, lines 46-48 and the standard plot of Fig.1).

6. Claims 22-31 are obvious over Carlson as applied in the immediately preceding paragraph and further in view of the admitted prior art as set forth at page 5, lines 7-17 of the specification.

Preceding paragraph 5 discloses immunoassay method but do not disclose calculating TEQ.

Admitted prior art disclose that calculation of TEQ value in immunoassay detection of dioxins is common and know in the art for dioxin determination (Specification, page 5, lines 7-17).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of the instant invention to include calculation of TEQ value in the method of Carlson et al for determining amount of dioxins in a sample.

Response to Argument

7. Applicant's arguments filed 5/4/06 have been fully considered, and are persuasive to overcome double patenting rejection and the rejections under 35 USC 112 and 35 USC 102, but they are not persuasive to overcome the rejections under 35 USC 103.

In view of amendments to claims, a new rejection is made over Carlson et al. under 35 USC 103 as described in paragraphs 5 and 6. With regard to Applicants' argument regarding the control standard, the use of control (standard) to obtain a

calibration curve is a well known requirement for the performance of an immunoassay and therefore the use of such a calibration curve by Carlson is implied. Since the competitor and analyte antigens bind similarly to the antibody, it would be presumed that either the analyte antigen or the competitor antigen could function equivalently as a control standard and an improved assay sensitivity is to be expected from the use of the competitor of Formula 1 of Carlson et al. (See Carlson et al., col. 4, lines 46-48 and the standard plot of Fig.1).

Conclusion

8. No claims are allowed.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


SHAFIQUL HAQ
EXAMINER
ART UNIT 1641

 08/22/01
LONG V. LE
SUPERVISORY PATENT EXAMINER
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